**IN THE UNITED STATES DISTRICT COURT**
**FOR THE WESTERN DISTRICT OF NORTH CAROLINA**
**CHARLOTTE DIVISION**

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| **UNITED STATES OF AMERICA, *ex rel.* TARYN HARTNETT and DANA SCHOCHED,**<br><br>**Plaintiffs,**<br><br>**vs.**<br><br>**PHYSICIANS CHOICE LABORATORY SERVICES, LLC, DOUGLAS SMITH, PHILIP MCHUGH AND MANOJ KUMAR,**<br><br>**Defendants.** | **CIVIL FILE NO. 3:17-CV-37**<br><br>(Consolidated with No. 3:17cv46) |

**UNITED STATES COMPLAINT IN INTERVENTION**

The United States of America (the "United States") brings this action to recover losses from false claims submitted to the Medicare program as a result of a fraudulent course of conduct by Defendants Physicians Choice Laboratory Services, LLC ("PCLS"), Douglas Smith ("Smith"), Philip McHugh ("McHugh") and Manoj Kumar ("Kumar") (collectively "Defendants"). Defendants knowingly and willfully offered and/or paid kickbacks to physician practices to induce physicians to refer urine samples to PCLS for large and medically unnecessary panels of urine drug tests ("UDTs"). These kickbacks resulted in false claims submitted to Medicare, which caused the federal government to pay more than $6.5 million to PCLS for excessive UDTs. Defendants paid kickbacks in the form of cash payments, loans, office equipment, and computer hardware, software and supporting technical services. Defendants intended to induce physicians to order excessive UDTs from PCLS in exchange for

these benefits in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). Defendants submitted false claims to the United States in violation of the False Claims Act ("FCA"), 31 U.S.C. §§3729-3733, and common law.

## I. NATURE OF ACTION

1. The United States brings this action against Defendants pursuant to the FCA, 31 U.S.C. §§ 3729-3733, seeking treble damages and civil penalties, and also under common law theories of liability.

2. James Jenkins, Elizabeth Coyle, Elizabeth Merry, Taryn Hartnett and Dana Shoched filed two separate complaints on behalf of the United States under the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1). The United States files this Complaint in Intervention as to Defendants PCLS, Smith, McHugh and Kumar pursuant to 31 U.S.C. § 3730(b)(3).

3. Defendant PCLS was founded in 2009 by Defendants Smith and McHugh as well as Marcus Sowinsky ("Sowinsky"). Within a few years, PCLS had grown into a large independent diagnostic laboratory specializing in UDTs. From 2009 to 2014, PCLS's annual reimbursements from Medicare climbed from just over $236,000 to over $40 million per year. In total, PCLS received over $136 million in payments from Medicare.

4. PCLS's business model relied upon convincing providers to order large panels of UDTs for their entire patient populations without regard to individual medical necessity for each patient. PCLS used aggressive marketing practices and incentives to convince physicians to use its services and to order large panels of expensive UDTs.

5. In addition, Defendants Smith, McHugh and Kumar provided additional financial benefits to potential PCLS customers to induce them to order large panels of expensive UDTs from PCLS in violation of the AKS, 42 U.S.C. § 1320a-7b(b).

6. Defendants used a variety of kickback schemes to induce physicians to routinely order excessive amounts of UDTs from PCLS for all patients regardless of individual patient assessment or need. Among the kickbacks Defendants paid physicians were cash payments, reimbursement of practice expenses, computer hardware and software, technical support for computer software, loans, and the provision of diagnostic equipment and associated services that allowed physician practices to generate income from conducting their own tests. Defendants intended to induce physicians to use PCLS services and order excessive UDTs in exchange for these benefits. After Defendants provided these benefits to physicians, the physicians ordered excessive UDTs from PCLS.

7. In addition, PCLS entered into an illegal contract with Kumar, pursuant to which Kumar was paid a commission based on the percentage of PCLS's revenue in exchange for Kumar arranging for, and recommending, that physician practices Kumar managed order tests from PCLS. The AKS prohibits a person from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of any "good" or "service" reimbursed by a federal health program. 42 U.S.C. §1320a-7b(b)(1)(B). The AKS likewise prohibits PCLS from paying such remuneration. *Id.* Defendant McHugh helped negotiate this agreement on behalf of PCLS. Defendants Kumar, McHugh and PCLS knowingly entered into contracts that violated the AKS.

8. PCLS then submitted claims for payment to Medicare for the UDTs conducted on the samples sent from these physicians. Smith, McHugh and Kumar knew that PCLS could not

submit claims to Medicare for tests on samples from physicians obtained in violation of the AKS; therefore, Smith, McHugh and Kumar caused the submission of false and fraudulent claims in violation of the FCA.

## II. JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a plaintiff pursuant to the FCA.

10. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide services of process and because Defendants can be found in, and/or have, transacted business in the Western District of North Carolina.

11. Venue is proper in the Western District of North Carolina under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because Defendants can be found in, and/or have, transacted business in this district. Defendants regularly conducted substantial business within this district.

## III. PARTIES

12. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS"), formerly known as the Health Care Financing Administrations ("HCFA"), on behalf of the Medicare program.

13. Relator James D. Jenkins is a resident of Knoxville, Tennessee and worked for Southeast Spine and Pain Associates, LLC.

14. Relator Elizabeth Coyle is a resident of Louisville, Kentucky and worked at New Phase Research and Development as a clinical research coordinator.

15. Relator Elizabeth Merry is a resident of Knoxville, Tennessee and worked for Complete Family Care, PLLC.

16. Relator Taryn Hartnett resides in Wellington, Florida, and worked for Defendant Douglas Smith, assisting him in running several of his businesses.

17. Relator Dana Shoched is a resident of Lambertville, Michigan and is a former sales representative for Defendant PCLS.

18. Defendant PCLS is a Florida limited liability company and was an independent clinical laboratory operating in Charlotte, North Carolina, and later moving to Rock Hill, South Carolina.

19. Defendant Douglas Smith is a resident of Charlotte, North Carolina and co-founder and partial owner of PCLS. He was a medical doctor in Florida before he lost his license on or around December 21, 2009. Smith has extensive experience in the health care field, having been a medical doctor and then starting several businesses that provided services to medical providers.

20. Defendant Phil McHugh is a resident of Charlotte, North Carolina and co-founder and partial owner of PCLS. McHugh was the CEO of PCLS and in charge of its sales department. Before founding PCLS, McHugh provided management services to medical providers in the pain management field.

21. Defendant Manoj Kumar is a resident of Fort Worth, Texas, and was an independent contractor and later an employee of PCLS. Kumar entered an independent contract arrangement pursuant to which he was paid a percentage of revenue for tests run on all urine

samples from physician practices he managed. Kumar has extensive experience in the health care field. He has owned several businesses providing management and billing services to health care providers.

22. Various other individuals not made defendants in this Complaint participated in PCLS's business practices described in this complaint.

## IV. THE LAW

### The False Claims Act

23. The False Claims Act provides, in pertinent part, that any person who:

> "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
> (C) conspires to commit a violation of subparagraph (A) [or] (B)….
> is liable to the United States Government [for statutory damage and such penalties as are allowed by law]." 31 U.S.C. §§ 3729(a)(1)-(3), as amended by 31 U.S.C. §§ 3729(a)(1)(A)-(C) (2010).

24. The False Claims Act further provides that "knowing" and "knowingly:"

> "(A) means that a person, with respect to information-
> i. has actual knowledge of the information;
> ii. acts in deliberate ignorance of the truth or falsity of the information; or
> iii. acts in reckless disregard of the truth or falsity of the information; and
> (B) requires no proof of specific intent to defraud."

**25.** The False Claims Act, 31 U.S.C. 3729(a)(1), provides that any person who violates the Act is liable to the United States Government for three times the amount of damages which the Government sustains because of the act of that person, plus a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.3(a)(9) (setting forth the civil penalties level of not

less than $5,500 and not more than $11,000 for violation of the FCA during the relevant time period of this case).

**The Anti-Kickback Statute**

26. The AKS arose out of Congressional concern that providing things of value to those who can influence health care decisions may corrupt professional judgment and result in federal funds being diverted to pay for goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. The AKS prohibits the payment of kickbacks to protect the integrity of federal healthcare programs. *See* Social Security Amendment of 1972, Pub. L. No 92-603, §§ 242(b) and (c), 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

27. The AKS prohibits any person or entity from soliciting, receiving, offering, or paying any remuneration to induce a person to, or reward a person for referring, recommending, or arranging for the purchase of any item or service for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

> b. Illegal Remunerations
>
> > (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
> >
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than ten years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof,
>
> shall be fined not more than $100,000 and imprisoned for not more than ten years, or both.

28. The AKS not only prohibits outright bribes to physicians, but also prohibits offering or paying any remuneration to physicians or others who can influence referral decisions, if one purpose of the remuneration is to induce referrals for goods or services for which payment might be made by Federal health care programs. Claims that include items or services resulting from violation of the AKS are false and fraudulent under the FCA. 42 U.S.C. § 1320a-7b(g).

29. The AKS has been the subject of multiple special fraud alerts and advisory opinions from the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG").

30. Moreover, activities of clinical laboratories have been so problematic that HHS-OIG has issued specific guidance with respect to such businesses.

31. The AKS and its application to relationships between physicians and clinical laboratories was the subject of one of HHS-OIG's first Special Fraud Alerts in 1994. *See* HHS-OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (October 2, 1994, *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletin/121994.html.

32. HHS-OIG stated that "[s]ince the physician, not the patient, generally selects the clinical laboratory, it is essential that the physician's decision regarding where to refer specimens is based only on the best interest of the patient." HHS-OIG went on to warn that "[w]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral business" and that "[t]he same is true whenever a referral source solicits anything of value from the laboratory."

33. HHS-OIG specifically noted that "provision of computers, or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work" could constitute an inducement in violation of the AKS.

34. In June 2014, HHS-OIG issued another special fraud alert focused on laboratory payments to referring physicians. *See,* Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014, *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/oig_sfa_laboratory_payments_06252014.pdf*).

35. HHS-OIG summarized the many negative effects of inducement payments to referral sources:

> "..such transfers of value may induce physicians to order tests from a laboratory that provides them with remuneration, rather than the laboratory that provides the best, most clinically appropriate service. Such transfers of value may also induce physicians to order more laboratory tests than are medically necessary, particularly when the transfers in value are tied to, or take into account, the volume or value of the business generated by the physician."

36. HHS-OIG noted that, although the legality of these arrangements depended on the intent of the parties, "[s]uch intent may be evidenced by the arrangement's characteristics,

including its legal structure, its operational safeguards, and the actual conduct of the parties to the arrangement."

37. The use of independent contractor sales agents has also been the subject of several HHS-OIG advisory opinions. *See,* HHS-OIG Advisory Opinion No. 98-10 (Issued August 31, 1998), *available at:* https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_10.htm; HHS-OIG Advisory Opinion No. 99-3 (Issued on March 23, 1999) *available at:* https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_3.htm

38. HHS-OIG noted that "any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal healthcare program potentially implicates the anti-kickback statute…" and that HHS-OIG "has a longstanding concern with independent sales agency agreements." HHS-OIG Advisory Opinion No. 98-10.

39. HHS-OIG stated that "percentage compensation arrangements are potentially abusive, however, because they provide financial incentives that may encourage overutilization of items and services and may increase program costs." *Id.* HHS-OIG described additional characteristics of certain independent sales agency agreements that are associated with increased program abuse and therefore, more likely implicate the anti-kickback statute including:

- compensation based on percentage of sales;
- direct billing of a Federal health care program by the Seller for the item or service sold by the sales agent;
- direct contract between the sales agent and physicians in a position to order items or services that are then paid for by a Federal health care program;
- direct contact between the sales agent and Federal healthcare program beneficiaries;
- use of sales agents who are healthcare professionals or person in a similar position to exert undue influence on purchasers or patients; or
- marketing of items or services that are separately reimbursable by a Federal health care program (e.g., items or services not bundled with items or services covered by a DRG payment), whether on the basis of charges or costs.

*Id.*

**The Medicare Program**

40. In 1965 Congress enacted Title XVII of the Social Security Act, which established the Medicare Program to provide health insurance to the elderly and disabled.

41. Payment from the Medicare Program comes from a trust fund – known as the Medicare Trust Fund – which is funded through payroll deductions taken from the work force and from government contributions.

42. Medicare is administered by the CMS, a division within the United States Department of Health and Human Services.

43. Medicare now has four parts: Part A (Hospital Insurance); Part B (Medical Insurance); Part C (Managed Care Plans); and the Part D (Prescription Drug) Program.

44. This case involves claims submitted by PCLS to Medicare Part B, which covers certain medical services, such as clinical laboratory test services, furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k(a)(2)(B).

45. Medicare Part B pays for covered health services and supplies only when they are medically necessary for the diagnosis or treatment of illness or injury. 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B… for any expenses incurred for items or services… which … are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k)(1).

46. The Secretary of HHS ("Secretary") is responsible for specifying service covered under the "reasonable and necessary" standard, and has wide discretion in selecting the means of

doing so. *See* 42 U.S.C. § 1395ff(a). Typically, the Secretary acts through formal regulations and sub-regulatory guidance.

47. The Secretary provides guidance to eligible providers pursuant to a series of Manuals, published by CMS, which are available to the public on the Internet.

48. To participate in the Medicare program as a new enrollee, clinical laboratories such as PCLS must submit a Medicare Enrollment Application, CMS Form-885B. Laboratories also complete Form 855-B to change information or to reactivate, revalidate and/or terminate Medicare enrollment.

49. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).

50. Form 855-B requires, among other things, signatories to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier… I understand that payment of a claim by Medicare is conditioned upon the claims and underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable condition of participation in Medicare.
>
> ****
>
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate or reckless disregard for their truth or falsity.

51. An authorized official must sign the "Certification Section" in Section 15 of the Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare Program." *Id.*

52. Defendant McHugh signed the certification statement in Section 15 of form 855B, indicating he understood that the laboratory was required to comply with Medicare law, regulations and program instructions, which include, but are not limited to, the AKS.

53. A National Provider Number ("NPI") is a standard and unique identifier for health care providers. All providers and practitioners must have an assigned NPI number before enrolling in Medicare.

54. At all times relevant to this complaint, CMS contracted with private contractors, referred to as Medicare Administrative Contractors ("MACs"), to act as agents in reviewing and paying claims submitted by healthcare providers.

55. To obtain Medicare reimbursement for certain outpatient items or services, providers and suppliers submit a claim form known as a CMS 1500 form ("CMS 1500"), or its electronic equivalent, to the MAC. Among the information provided on the CMS 1500 are the NPI numbers for the entity submitting the claims, referred to as the "billing provider" (PCLS in this case) and the NPI number for the physician ordering the tests, referred to as the "rendering provider" (in this case the practitioner that ordered the UDT from PCLS, also called the referring physician).

56. Also included in the CMS 1500 are five-digit codes called Current Procedural Terminology Code ("CPT Codes"), and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which the entity submitting the claim is seeking payment.

57. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and NPI number for the referring physician. 42 U.S.C. § 1395l(q)(1).

58. When submitting claims to Medicare, providers certify on the CMS 1500, *inter alia*, that: (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information in the claim form is "true, accurate, and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, that any false claims, statement, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws." After a February 2012 revision to the CMS 1500, providers further certify that their claims comply "with all applicable Medicare… laws, regulations, and program instructions for payment including, but not limited to, the Federal anti-kickback statute and the Physician Self-Referral Law (commonly known as the Stark Law)."

59. Because it is not feasible for the Medicare program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and relies on providers to submit truthful and accurate certifications and claims.

60. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider in reliance on the foregoing certifications, without any review of the supporting documents, including the medical records.

61. During all times relevant to this case, Palmetto GBA was the MAC to which PCLS submitted its claims for UDT services.

62. During the relevant time period, PCLS billed Medicare under Part B clinical laboratory services by submitting claims for reimbursement to Palmetto GBA.

## Medicare Coverage for Laboratory Tests

63. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), 42 U.S.C. § 263a, as set forth at 42 C.F.R. § Part 493.

64. Medicare Part B pays for covered diagnostic laboratory tests that are furnished by a laboratory. 42 C.F.R. § 410.32(d)(v). "Clinical laboratory services involve the… examination of materials derived from the human body for diagnosis, prevention, or treatment of a disease or assessment of a medical condition." Medicare Benefit Policy Manual ("MBPM"), (Pub. 100-02), Ch. 15 § 80.1., available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf, last visited on June 19, 2019.

65. Medicare Part B covers only services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. *See*, 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B… for any expenses incurred for items or services… which… are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]")

66. Medicare regulations make clear that: (1) laboratory tests must be ordered by the physician treating the patient for the treatment of a specific illness or injury; (2) laboratory tests ordered that are not individualized to a patient need (or for which the need is not documented in the patient chart) are not covered services; and (3) claims for such laboratory services that do not meet these requirements are ineligible for payment and must be denied. *See* 42 C.F.R. § 410.32.

67. Pursuant to 42 C.F.R. § 410.32(a), all diagnostic tests "must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes the consultation or

treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical condition. Tests not ordered by the physician who is treating the beneficiary are not reasonable or necessary." The MBPMs "Requirements for Ordering and Following Orders for Diagnostic Tests" define an "order" as "a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary…[T]he physician must clearly document in the medical record his or her intent that the test be performed." MBPM, Ch. 15, Section 80.6.1.

68. Medicare regulations expressly state that a laboratory's claim for service will be denied if there is not sufficient documentation in the patient's medical record to establish that the service was reasonable and necessary. 42 C.F.R. § 410.32(d)(3).

69. Medicare regulations further empower laboratories to request documentation from physicians regarding medical necessity:

> (iii) **Medical necessity.** The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary.

42 C.F.R. § 41032(d)(3).

**HHS-OIG Guidance to Clinical Laboratories**

70. Additionally, HHS-OIG issued specific guidance to clinical laboratories with regard to physician or practitioner orders. *See*, Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45076 (Aug. 24, 1998), available at https://oig.hhs.gov/authorities/docs/cpglab.pdf.

71. Among other things, HHS-OIG emphasized the need for an independent medical necessity determination for each test ordered, that Medicare does not pay for screening tests, and that the use of a standing order all too often leads to abusive practices. *Id.* at 45079, 45081.

## V. FACTUAL BACKGROUND

### A. Urine Drug Testing

72. UDTs are used to determine the presence or absence of drugs or metabolites, also known as analytes, in a patient's system.

73. UDTs are performed in a number of contexts, but in recent years with the advent of pain management clinics that routinely prescribe opioid pain medication, laboratories began marketing sophisticated and expensive drug tests to practitioners working in this field.

74. Properly used, UDTs can be an effective tool to monitor a patient's compliance with their prescribed drug treatment or taking or abusing drugs that have not been prescribed.

75. Broadly speaking, UDTs can be either qualitative, which provides a positive or negative result (that is the presence or absence of a drug or metabolite), or quantitative, which provides a numerical representation of the amount of drug or metabolite in the patient's system.[1]

76. Quantitative drug testing is the most sophisticated, labor intensive and expensive.

77. Urine is the most common medium used for drug testing, and was the most prevalent at PCLS.

78. Drug tests are often widely categorized between point-of-care ("POC") tests and tests conducted in independent clinical laboratories.

79. POC tests are performed at a physician's office or clinic using test cups or relatively simple machines that provide qualitative (positive or negative) results for the drugs being tested. Drug test cups have a number of built-in drug test strips, each of which tests for a

[1] Qualitative and quantitative testing are also called "presumptive" and "definitive" testing, respectively, in coverage determination issued by Medicare contractors. See Local Coverage Determination L35724, "Lab: Controlled Substance Monitoring and Drugs of Abuse Testing," https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35724&ContrId=378&ver=59&ContrVer=1&CntrctrSelected=378*1&Cntrctr=378&LCntrctr=378*1%7c379*1%7c380*1%7c381*1&DocType=2&bc=AgACAAQAAAAA& *available at* https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=54799

specific drug or drug class. A test strip will turn a color if the drug is present. The more complex machines, often referred to as desktop or benchtop analyzers, are somewhat more sophisticated and often have the capacity to run tests on more than one urine sample at a time.

80. Under CLIA, CMS oversees all laboratory testing services. UDT performed using POC drug testing strips and test cups is generally categorized as "CLIA-waived" and requires little training to conduct. CLIA-waived tests are categorized as simple laboratory examination and procedures that have an insignificant risk of an erroneous result or pose no harm to the patient if the test is performed incorrectly. 43 C.F.R. § 493.15(b). To perform CLIA-waived tests, physicians need to enroll in CLIA and obtain a waiver. 43 C.F.R. § 493.35. To operate a benchtop or desktop analyzer, physician practices are generally required to obtain a CLIA certification to perform moderate- or high-complexity laboratory tests. 42 C.F.R. § 493.20, 493.25.

81. Up until January, 1, 2011, many physician practices submitted claims for multiple units of drug testing when using test cups, allowing them to obtain very high reimbursement from Medicare. Because test cups are relatively inexpensive, POC tests using cups was a significant profit source for physicians and other practitioners.

82. Medicare changed the rules in 2011, however, strictly limiting what providers could bill for POC testing to one code per patient encounter. Further, Medicare cut the reimbursement rate for CLIA-waived and moderately complex tests. Medicare created two new HCPCS codes – G0434 for CLIA-waived and moderately complex tests that paid approximately $20 per patient encounter, and G0431 for high complexity tests that paid approximately $100 per patient encounter.

83. UDT at laboratories is generally performed by more precise methodologies, such as column chromatography in combination with mass spectrometry. PCLS used liquid column chromatography in combination with mass spectrometry, more commonly referred to as LC-MS. This testing methodology provided quantitative results, which identify the concentration of a drug or metabolite in the patient's sample.

84. PCLS submitted claims for the quantitative tests using CPT codes assigned for each drug or class of drugs tested, often billing multiple units for a CPT code.

85. PCLS's technology allowed it to conduct quantitative tests for multiple drugs during a single run of a urine sample through the LC-MS machines.

86. POC tests, either cups or analyzer, provide practitioners with rapid positive or negative test results that show whether a patient has tested positive for drugs that have been prescribed, and negative for drugs that were not prescribed. A negative result for a prescribed drug or a positive result for an illicit drug or a drug not prescribed will warrant additional investigation by the practitioner, which may include questioning the patient or, under some circumstances, confirmatory testing via more sophisticated and accurate testing methodologies.

87. Expected positives and negative results on POC tests, however, do not in general warrant additional testing absent other factors like aberrant patient behavior, unexpected clinical presentation or a history of drug abuse by the patient. The medical reasonableness and necessity of such additional testing, however, must be evaluated by the presentation and physician assessment of the individual patient and their specific illness, symptom, complaint, or injury.

88. A positive result for a prescribed drug and a negative result for a non-prescribed or illicit drug is considered an expected result.

89. If a POC test is negative for an illicit drug or drug not prescribed, and positive for prescribed drug, and there is nothing in the patient's presentation or history to indicate additional risk of abuse of that drug, then there is no specific illness, symptom, complaint, or injury for which definitive UDT would be reasonable and necessary for the treatment or diagnosis of that patient.

90. In all situations, quantitative UDT should be utilized only to the limited extent it is necessary for an individual patient, based on that individual's qualitative test results and other factors specific to that patient. Widespread, quantitative UDT should not be ordered as a matter of course.

**B. Reimbursement for Urine Drug Tests**

91. Medicare pays different amounts for different types of UDTs. Additionally, Medicare's reimbursement rates have changed over time, creating different financial incentives for practitioners and laboratories.

92. Since January 2011, Medicare has required that POC tests using test cups be billed using HCPCS code G0434, which reimburses at a fixed rate of about $20 to $25 per patient encounter – regardless of the number of substances tested with the cup.

93. Additionally, in January 2011, Medicare required that moderate complexity tests as categorized by the FDA also be billed under G0434 and reimbursed at about $20 to $25 per patient encounter. High complexity tests, often lab developed tests, qualified for a higher reimbursement of approximately $100 per patient encounter under HCPCS code G0431.

94. Generally, HCPCS code G0434 and G0431 applied to qualitative drug tests.

95. Quantitative tests of the type conducted by PCLS on LC-MS machines qualified for reimbursement under individual CPT codes for each type of drug tested. For example, a test

for an opioid such as oxycodone could be billed under CPT code 83925, while a benzodiazepine could be billed under CPT code 80154. Medicare paid a certain amount for each code submitted in the claims.

96. Additionally, a provider could bill more than one unit on the CPT code. If two units were included in the claim, the provider would be paid twice for the CPT code.

97. PCLS submitted claims to Medicare for quantitative testing using the specific CPT codes applicable to the drug class, often with multiple units.

98. In addition to CPT codes that identify the specific drug test, there are CPT codes that identify the testing methodology. Such codes are supposed to be used when a laboratory uses that methodology to test for a drug that does not otherwise have a CPT code assigned to it. PCLS used these technology-specific codes when testing for drugs that did not have a specific code assigned to them.

99. In many cases PCLS billed over 20 CPT codes for a single test.

**C. PCLS Business Practices**

100. PCLS was established in 2009 by Defendants Smith and McHugh, along with Sowinsky.

101. Smith, McHugh and Sowinsky all had experience in other health care companies before starting PCLS.

102. McHugh assisted pain management doctors with the management of their practices.

103. Before PCLS was established, Smith and Sowinsky had gone into business together for a brief time to offer services to medical practices, including software to write electronic prescriptions.

104. McHugh was familiar with the work of UDT labs from his work with pain management practices. McHugh knew Sowinsky because some of the doctors he worked with were customers of Smith and Sowinsky's business.

105. McHugh approached Smith and Sowinsky with the idea of establishing PCLS to conduct quantitative UDTs.

106. McHugh and Smith were heavily involved in establishing PCLS's business plan and marketing strategy. McHugh served as PCLS's CFO and was responsible for day-to-day operations. McHugh was also in charge of the sales force.

107. PCLS was established to market and conduct quantitative drug testing.

108. PCLS focused its early marketing activities on large pain management practices. Smith and McHugh were familiar with pain management practices from their previous work and recognized that these practices would be fertile ground for UDT marketing.

109. To set up an account, PCLS required providers to sign a "Provider Acknowledgment Form" ("PAF") that served two purposes. First, after signing the PAF, the provider's signature was "on file" with PCLS, and PCLS did not then require the physician's signature on individual UDT orders. Second, the PAF established a panel of UDTs that the laboratory would run on every sample referred by the provider unless the provider checked a box on the requisition form telling PCLS to conduct tests different from those established in the PAF.

110. Once doctors signed on to PCLS, every patient received the same extensive panel of tests every time the patient was tested.

111. The PAF effectively established a default pursuant to which every patient sample from the physician would be tested for the full panel of tests reflected in the PAF unless the physician made a specific choice to override that default setting.

112. PCLS's method included the following steps:

a) Obtain up-front authorization to run the extensive panel of UDTs for every patient each time a sample was submitted for a patient;
b) Obtain the physician's signature on file so that the physician would not have to sign each requisition;
c) Provide preprinted requisition forms to the physician that had the pre-selected extensive panel pre-checked;
d) Provide collectors to high-volume physicians that collected the urine samples and attached the pre-printed requisition to every sample sent to PCLS.

113. PCLS thus caused physicians to sign on for extensive panels of UDTs for all of their patients without any individualized medical decision-making by the physician for the particular patient.

114. Once a doctor signed onto the PAF, PCLS would run the same large battery of UDTs on a patient with no history of drug abuse, who had been fully compliant with the prescribed medication regimen, and who passed POC drug tests, as they would a patient with extensive history of drug abuse who also failed POC drug tests administered in the doctor's office.

115. Doctors were urged by PCLS sales agents to conduct quantitative testing for all drugs in the panel even if the POC test showed negative for illicit or non-prescribed drugs.

116. At the urging of PCLS sales agents, doctors routinely submitted PAFs that established a standing order for all of their patients for 20 to 30 drugs, including drugs such as cocaine and PCP.

117. Diagnostic testing according to a pre-set panel results in significant potential for billing abuse. Recognizing the high risk that physicians will routinely order unnecessary tests when ordering a panel, HHS-OIG has advised, "[t]he laboratory should construct the requisition form to ensure that the physician or other authorized individual has made an independent

medical necessity decision with regard to each test the laboratory will bill." Fed. Reg. Vol. 63, No. 163, August 24, 1998, 45079.

118. HHS-OIG also said that laboratories allowing physicians to make customized profiles for a panel of tests should provide an annual notice that, among other things, explains the Medicare reimbursement paid for each component of such profile. *Id.*

119. In 2012, an outside firm conducted an audit of PCLS and advised that HHS-OIG "warns that the ordering and performance of custom panels may lead to the submittal of claims for medically unnecessary testing." The audit firm advised PCLS to revise its custom profile notification form to include, among other things, "the corresponding procedure codes and associated Medicare reimbursement for all component tests…"

120. The audit firm went on to recommend that PCLS provide all referring physicians an annual notice that includes the suggested information, and that all referring physicians sign and return the notice.

121. The next year, in the 2013 audit report, the auditor again told PCLS that it should issue the above-described annual notice and warned, "[c]ontinued failure to distribute such an annual notice will significantly diminish the effectiveness of PCLS' compliance program."

122. The next year, in the 2014 audit report, the auditor again addressed PCLS's custom panel program and stated, "[t]he following recommendations are nearly identical to the recommendation concerning custom panels included in the previous annual compliance audit report. During the past year, PCLS chose not to implement policies and procedures concerning an annual physician acknowledgment as recommended last year."

123. Some PCLS compliance officials sought to implement the auditor's recommendations, but McHugh and other sales force managers opposed including this information.

124. Defendants never implemented annual notices to physicians regarding their custom panels and recommended by HHS-OIG and their own internal auditor. Instead, PCLS's PAFs, requisition forms and marketing practices were designed to encourage full-panel testing of all patients within a physician's practice with no individualized medical decision-making or patient assessment.

125. One challenge faced by PCLS and its agents was how to convince doctors to use PCLS for these excessive and expensive tests.

126. As described in more detail in this complaint, Defendants Smith, McHugh and Kumar engaged in additional inducement schemes, in violation of the AKS, to convince doctors to send samples to PCLS for extensive panel testing and without individualized medical decision making for each patient.

**D. Defendant Smith's Kickbacks to Pain Clinic**

127. Southeast Spine and Pain Associates ("SSPA"), formerly known as Advanced Pain Therapeutics ("APT"), was a high volume pain clinic in Knoxville, Tennessee.

128. In 2010, APT was owned by Dr. Allen Foster and his wife, Sonya Foster.

129. In 2010, PCLS was a new laboratory aggressively courting new clients.

130. APT was one of PCLS's biggest customers. In 2011 alone, PCLS billed over $1.6 million to Medicare in drugs tests from samples referred by APT.

131. In 2011, Dr. Foster plead guilty to health care fraud and was sentenced to a year in prison.

132. Dr. Foster's wife continued to operate the practice with a series of substitute doctors.

133. The practice quickly deteriorated under her management and referrals of UDTs to PCLS plummeted.

134. From January 2010 to June of 2012, APT's referrals resulted in nearly $900,000 in revenue to PCLS from Medicare alone.

135. From mid-June, 2012 to August 31, 2012, APT's referrals completely dried up resulting in no revenue to PCLS.

136. PCLS management, including Defendant Smith, was concerned about the fall in referrals from APT and tried to assist the practice to maintain the flow of referrals.

137. By mid-2012, Mrs. Foster wanted to sell the practice.

138. Defendant Smith arranged for one of his business associates, James Lord ("Lord"), to purchase the practice and begin referring samples to PCLS for UDTs again.

139. Lord, however, was not a medical practitioner, so Smith and Lord needed a straw-owner to appear on the relevant paperwork as the "owner" of the practice.

140. One of the physician's assistants at the practice acted as the straw-owner, but Lord controlled the practice in all respects and made the decisions on where the practice would send its urine samples for UDTs.

141. Lord entered an agreement to purchase Advanced Pain under the company name Optimed in or about August or September 2012, and renamed the practice SSPA.

142. To effect this purchase, Smith transferred $300,000 to Lord in two installments, one on August 28, 2012 for $50,000 and the other on September 10, 2012 for $250,000.

143. Lord then paid $200,000 to Mrs. Foster as a down payment for the practice and retained the other $100,000 that Smith had given him.

144. After Lord gained control of SSPA, practitioners at SSPA signed PAFs establishing a broad and expensive panel of tests to be run on samples sent to PCLS.

145. Referrals to PCLS immediately increased, resulting in over $473,000 in revenue to PCLS from Medicare claims alone from September 2012 through December 31, 2012.

146. Lord's practice continued referring to PCLS through July of 2014. In 2013, PCLS received over $1,496,000 from Medicare alone for tests conducted on referrals from SSPA. From January to July 2014 PCLS received an additional $776,000 from Medicare alone for tests conducted on referrals from SSPA.

147. In addition to the $300,000 Smith paid Lord, Smith also provided practice management software, referred to as MedX, and related computer hardware to SSPA.

148. MedX was a practice management software that included front desk check-in capability and patient flow tracking. It was a benefit to doctors because it assisted them in more efficiently running their practices.

149. In addition to the benefits to practice management, MedX allowed physicians to capture an additional revenue stream. MedX included a risk management program that asked questions of opioid patients to supposedly help determine if they were a diversion risk.

150. SSPA used the MedX program to have each patient take this test and then submitted claims to Medicare under CPT Code 96103. Medicare paid SSPA over $129,000 for claims submitted under this code.

151. Smith also paid technical support personnel to maintain the MedX hardware and software at SSPA.

152. Relator Hartnett worked for Smith for a period of time. In or around 2013, Smith told her that he did not worry about getting paid for MedX because the revenues to PCLS more than made up for it.

153. SSPA was able to obtain additional revenue using the software, hardware, and related support services provided by Defendant Smith.

154. Additionally, in September, 2012, just as Lord was taking control of SSPA, Smith purchased Lord a BMW automobile for $36,000.

155. Smith provided these multiple benefits to Lord to induce Lord to send UDT samples to PCLS in violation of the AKS.

156. From September 2012 to July 2014, after Smith gave Lord the $300,000, the BMW and the MedX software and continuing technical support, PCLS submitted over 8,700 claims to Medicare and was paid over $2.7 million for tests conducted on referrals from SSPA.

157. During this time period, Lord hired relator James Jenkins to assist in managing the practice. Lord told Jenkins he could do anything necessary to manage the practice except stop using PCLS for UDTs. Lord told Jenkins he had a relationship with Smith that required them to send the samples to PCLS.

158. In late July, 2014, SSPA stopped referring samples to PCLS after Lord had a falling out with Smith.

**E. Defendants McHugh and Kumar Provide Analyzers to Physicians**

159. McHugh and Kumar provided desktop UDT analyzers and related services to physicians in exchange for those physicians sending urine samples to PCLS for confirmation drug testing.

160. In early 2011, Kumar identified a method by which PCLS could help doctors obtain revenue by conducting in-office UDTs on analyzers that PCLS would help them obtain. PCLS agents, including McHugh and Kumar, developed a plan pursuant to which they would induce physicians to send urine samples to PCLS for quantitative testing in exchange for assistance with setting up an in-office qualitative testing program.

161. As described earlier in this Complaint, UDTs can be either qualitative (positive or negative results) or quantitative (providing specific quantities of drugs or metabolites in a patient's sample).

162. Qualitative tests can be conducted in a variety of ways, including simple CLIA-waived tests using cups that utilize built-in test strips, or more sophisticated tests conducted on desktop analyzers.

163. Until January 2011, physician practices could bill for multiple units of tests by using a single UDT cup that tested for multiple drug classes. Physicians could obtain over $200 in revenue by using a test cup that cost between $5 and $10. During this time, one popular inducement scheme was for laboratories to give physicians these test cups in exchange for the physician sending UDT samples to the lab for further quantitative tests.

164. In January 2011, CMS changed the rules for submitting claims for test cups to Medicare. First, CMS instituted a new HCPCS code, G0434, which paid only approximately $20. Second, CMS limited the use of this code to one unit per patient encounter.

165. Physicians were thus limited to only $20 in revenue when they used a cup to test patients for drug use.

166. Defendant Kumar recognized the practical implications of this change in the rules. Specifically, because physicians could no longer make a lot of money by testing with the cup, they would need to test with analyzers to make more money.

167. Kumar told McHugh and others:

> I would like to consider this a positive opportunity for PCLS to take a positive position of Premier Support and Excellence to our doctors and anticipated clients. The trend is clear – the great window of making money for the physicians via UDS screening is closing fast unless they keep pace with the changing scenario. I believe that this is a stage where we step in by offering them a package deal of basically setting up their Moderate Complexity Lab wherein they are assured that our lives are intertwined and that we are vested in their progress.

168. Kumar believed that if physicians used desktop analyzers they could bill Medicare for such tests under G0431, which paid over $100 per test.

169. Kumar further noted that "they [physicians] would be interested as that would allow them to continue billing and collecting $$."

170. Kumar was telling McHugh, Smith and other agents of PCLS that if PCLS assisted physicians in establishing a moderate complexity lab with their own analyzer in exchange for sending samples to PCLS for additional testing, PCLS's financial interest in obtaining more samples would be aligned with the physician's financial interest in conducting more tests on the equipment PCLS assisted the physician obtain.

171. Kumar concluded that to do this, Defendants McHugh and Sowinsky would need to: 1) aggressively negotiate on behalf of doctors for a great deal on analyzers and reagents; 2) obtain a toxicologist lab director to help run the analyzer; and 3) assist the physicians to get necessary certifications to conduct UDTs on analyzers and submit claims to Medicare and other insurers.

172. PCLS, McHugh, Kumar, Smith and other agents of the company devised a plan by which they could offer PCLS customers access to desktop analyzers to conduct point of care drug tests. Kumar, McHugh and others at PCLS also advised physicians that claims for such tests could be submitted to Medicare under HCPCS code G0431 to obtain payment for over $100 per test.

173. PCLS, McHugh, Kumar, Smith and other agents of the company believed other independent labs were offering physicians kickbacks to use their labs and that this analyzer program was a way to offer physicians similar kickbacks to use PCLS.

174. PCLS provided doctors with revenue projections showing how much money they could make by implementing this plan with PCLS.

175. Kumar and McHugh assisted multiple physicians obtain analyzers and establish in-house laboratories so that the physicians could bill Medicare for qualitative testing in exchange for sending the samples to PCLS for additional quantitative testing.

176. As described below, Kumar and McHugh induced doctors John Johnson and John Nickels to send urine samples to PCLS for UDTs by paying expenses associated with setting up Johnson's and Nickels's analyzer systems.

*1. McHugh and Kumar Provide Analyzer to John Johnson in Exchange for Referrals*

177. Dr. John Johnson ("Johnson") was a pain management doctor in Western Pennsylvania.

178. Johnson had a relationship with William Hughes ("Hughes") and his laboratory Universal Oral Fluids Laboratory ("UOFL"). Johnson provided saliva samples to UOFL for drug testing. Johnson was paid medical director fees and other money from UOFL for samples he sent to UOFL.

179. In or about 2010, Jeffrey Thomas ("Thomas"), a PCLS sales representative, met Hughes's wife, who was working as a sample collector in a physician's office.

180. Hughes called Thomas looking for a company to do quantitative testing on the saliva samples UOFL was receiving from doctors. UOFL did not have the ability to conduct quantitative testing on its own.

181. Thomas introduced Hughes to Defendant McHugh. Hughes and McHugh agreed that PCLS would conduct the quantitative testing on the samples from UOFL, while UOFL continued to do the qualitative testing.

182. In 2011, Hughes began developing the capacity to conduct quantitative testing at UOFL. This would allow Hughes to capture the revenue from the quantitative testing instead of PCLS.

183. McHugh was aware of the various inducements Hughes was providing to physicians.

184. McHugh and PCLS recognized that they would lose all of the UOFL business when UOFL started running quantitative tests.

185. PCLS sought to poach all of UOFL's clients. In November 2011, PCLS sent a letter to all of UOFL's clients, informing them that PCLS would no longer conduct quantitative testing for samples submitted through UOFL. PCLS then sought to obtain the direct business from those doctors from UOFL.

186. Johnson was one of the doctors that McHugh and Kumar wanted as a client and sought to lure away from UOFL.

187. About a year after Johnson starting using UOFL, McHugh contacted Johnson to attempt to get his business away from UOFL. Johnson stayed with UOFL. McHugh was aware

that Johnson was receiving financial benefits from UOFL, and Hughes told Johnson that he and PCLS could also provide such benefits but cover it up better for AKS considerations.

188. Johnson later ran into financial difficulties and an associate suggested he reach out to Kumar at PCLS.

189. On April 13, 2012, Kumar sent an email to Johnson summarizing the available options for the analyzer and lab, and stating, "Phil McHugh from PCLS and I will discuss all aspects of this lab and will get the show on the road most expeditiously."

190. McHugh and Kumar went to Pennsylvania for an in-person meeting with Johnson.

191. McHugh, Kumar and Johnson were the only attendees at this meeting. During the meeting, McHugh told Johnson that they would set him up with an analyzer and Johnson would send his samples on to PCLS so PCLS could get their money back. McHugh and Kumar wanted to provide the services to get Johnson's analyzer set up in exchange for Johnson sending samples to PCLS for quantitative testing.

192. McHugh, Kumar and Johnson agreed to proceed with this plan. Kumar and an associate named Elan Paul Colen ("Colen") were responsible for implementing the plan, which included obtaining the analyzer, obtaining the CLIA certification for Johnson's lab, and guiding Johnson and his staff through the entire process of setting up the lab. Colen worked under Kumar's direction.

193. On April 23, 2012, McHugh sent Kumar an email with an attached document entitled "Dr Johnson Lab List." The list included the following tasks:

> "lab setup contract (already with Steve)
> Check with criteria on PA Clia Lab director responsibilities
> Lab director paperwork and submittal
> Technical director visit, start SOP & over view of lab flow
> Olympus AU 400 contract signed with financing options
> LIS software with integration to EMR

Battery backup system purchased
DI Water system purchased and installed
2 Computer purchase, network, internet access
Lab build outs, walls, floor, electric, pluming, and tables.
Post Ad, hire MLT and data entry/sample assistant
Billing codes checked
Mr Reagon install Olympus and validate system
Accept samples

194. On April 26, 2012, Kumar wrote to Johnson, "[t]aken the last couple of days to put a plan in place, identify and allocate resources to ensure that the plan is executed with Military Presicion." Kumar goes on to note that "Phil [McHugh] has already made contact with the supplier of the Olympus Au400 and would have attractive financing options available."

195. While McHugh, Kumar and Colen established Johnson's lab, Johnson was concerned that Hughes would discover that Johnson was working with PCLS and would cut off Johnson's payments from UOFL.

196. For several months McHugh, Kumar and Colen worked to obtain Johnson's analyzer and set up his lab. Their work included negotiating all aspects of the analyzer and support services purchase, obtaining CLIA certification, and organizing all aspects of getting the lab up and running.

197. In August 2012, Kumar paid a $17,000 deposit for Johnson's analyzer.

198. In exchange for all of these benefits, Johnson began referring samples to PCLS for quantitative testing in mid-June 2012.

199. PCLS monitored the number of referrals Johnson was sending to the lab. In March 2013, Colen warned Johnson that his sample volume was not sufficient because it had decreased from the expected 200 samples per week.

200. Colen told Johnson that PCLS had informed Colen that Johnson had not supplied the promised number of samples.

201. Colen told Johnson this was an issue that needed to be addressed ASAP to get the analyzer program completed in Johnson's office.

202. In response Johnson promised to start sending more samples to PCLS.

203. From June 2012 to July 2013, PCLS submitted over 2,900 claims to Medicare for tests on samples referred by Johnson in exchange for the benefits McHugh and Kumar provided to him. Medicare paid PCLS over $770,000 for those claims.

*2. McHugh and Kumar Provide Analyzer to Dr. John Nickels*

204. Dr. John Nickels ("Nickels") was a pain management doctor in Cleveland Ohio. During the same time that McHugh and Kumar were setting up Dr. Johnson's lab, they were also setting up a lab for Nickels.

205. As with Johnson, McHugh and Kumar sought to induce Nickels to send samples for quantitative testing to PCLS by providing him an analyzer that allowed him to conduct and bill for qualitative testing from his office.

206. McHugh and Kumar arranged for Nickels to obtain an analyzer and agreed to pay for the analyzer and all expenses related to the analyzer. In exchange, Nickels agreed to send samples for quantitative testing to PCLS.

207. McHugh met with Nickels and a representative from an analyzer company to discuss how Nickels could use an analyzer for additional revenue.

208. In May 2012, in internal PCLS communications, Kumar and McHugh were asked if Nickels was still a priority to set up as a PCLS client. Kumar replied "[h]is [Nickels] lab is likely to be up and running by Mid-June. It is expected that he would switch to us at that stage or soon after." Kumar asked McHugh for his opinion in this email. McHugh responded "[y]es. Let's chat tomorrow."

209. McHugh and Kumar are confirming that Nickels is going to switch his UDT referrals to PCLS in exchange for them setting up his lab.

210. Nickels's arrangement for the analyzer involved no up-front costs. Instead, he was supposed to pay a certain amount per sample tested on the analyzer. This would allow Nickels to make a profit from the amount of the difference between the amount insurance providers, including Medicare, paid him for the tests and the amount he had to pay the analyzer company for running the test.

211. In reality, although Nickels paid the analyzer company to conduct the test, Kumar and McHugh reimbursed him for those as well as other expenses associated with running the analyzer. Nickels, therefore, paid no out-of-pocket costs for the analyzer or the testing, but received remuneration from Kumar and McHugh for doing nothing more than sending referrals to PCLS.

212. In August 2012, Nickels sent Kumar a list of expenses for the analyzer and lab that he expected Kumar and McHugh to pay. This lengthy list included several items of office overhead and a request for $2,208 for 92 tests run on the analyzer.

213. Nickels noted that his expenses for the month were $8,103.32, but that Kumar had already paid him $3,000 leaving a balance owed of $5,103.32. Nickels suggested Kumar send him $9,000 to cover the balance and the next month's expenses.

214. Responding to Nickels on August 16, 2012, Kumar said that he would "personally deliver" the requested funds. Kumar delivered the requested $9,000 on September 11, 2012.

215. In November 2012, Nickels requested another payment from Kumar to reimburse him for expenses related to the analyzer. Nickels noted that he was requesting this money "per [his] agreement with Phil [McHugh]."

216. McHugh and Kumar paid Nickels from personal accounts to conceal their activities from PCLS Compliance.

217. In January 2013, Nickels requested another payment from Kumar for expenses related to his practice and the analyzer.

218. Nickels began sending samples to PCLS for quantitative testing in June 2012.

219. From June 2012 to July 2013, PCLS submitted 323 claims to Medicare for UDTs conducted on samples provided by Nickels in exchange for Kumar and McHugh paying the expenses related to Nickels's analyzer. Medicare paid PCLS over $71,000 for these claims.

**F. Kumar Receives Remuneration for Providing Samples from Physicians**

220. In addition to assisting McHugh in the above described inducement schemes, Kumar served as a contract sales agent for PCLS.

221. McHugh had known Kumar for approximately nine months before McHugh started PCLS with Smith. McHugh hoped that Kumar could direct samples from a large practice he managed in 2009. The practice, however, disintegrated. Two doctors from this practice, Dr. Gregory Masimore ("Masimore") and Dr. Yunis Shah ("Shah"), went on their own.

222. Kumar began managing Masimore's and Shah's practices.

223. McHugh knew that Kumar managed these practices and could direct UDT referrals from these practices to PCLS.

224. In late 2010, Kumar wrote to Phil McHugh, making his argument to be an independent contractor sales representative for PCLS. He noted that he has already signed on Masimore, and that Shah "will go the way I advise…". Kumar requested that he be paid a commission for samples from those practices.

225. Kumar and PCLS entered a contract pursuant to which Kumar would be paid a commission based, in part, on a percent of PCLS's collections from Medicare for tests run on samples from Masimore and Shah.

226. McHugh and PCLS expected Kumar to deliver samples from Masimore and Shah in exchange for these commission payments.

227. Kumar recommended to Masimore and Shah they use PCLS services.

228. Neither Masimore nor Shah had heard of PCLS until Kumar told them they should use PCLS. Both used PCLS based on Kumar's recommendation.

229. Masimore and Shah then selected their standing panel of tests after consultation with PCLS sales representatives.

230. Masimore sent samples to PCLS for testing from November 2011 through November 2015. During this time, PCLS submitted 3,441 claims to Medicare for testing on samples referred to PCLS by Masimore. Medicare paid PCLS over $1.1 million for these claims.

231. Shah sent samples to PCLS for testing from January 2011 through January 2015. During this time, PCLS submitted 3,536 claims to Medicare for testing on samples referred to PCLS by Shah. Medicare paid PCLS over $980,000 for these claims.

232. PCLS paid Kumar over $600,000 in commissions for testing on samples from Masimore and Shah.

**G. McHugh lends $2 million to Pain Management Doctor**

233. Orlando Florete ("Florete") is a pain management doctor in Florida.

234. Like Doctors Johnson and Nickels, Florete was a customer of Hughes and UOFL. Florete was also paid as a laboratory director for UOFL.

235. Florete met McHugh and Kumar through a mutual friend.

236. Florete's practice was having financial problems when Florete met McHugh and Kumar in 2013, and Florete was heavily in debt to Hughes.

237. In 2013, McHugh and Kumar traveled to Jacksonville, Florida to meet with Florete and solicit his business.

238. Florete informed McHugh that he was having financial problems and needed money.

239. Florete, Kumar and McHugh also arranged to install an analyzer in Florete's practice so that Florete could capture revenues from conducting point-of-care tests in his office.

240. Florete agreed to begin sending samples to PCLS as he and McHugh began negotiating a loan from McHugh to Florete.

241. Based on information and belief, Florete could not have obtained a commercial loan in an arms-length transaction due to his financial situation.

242. On October 18, 2013, Florete and McHugh entered into a loan agreement and McHugh wired Florete $1.7 million. On March 24, 2013, McHugh provided Florete an additional $300,000.

243. McHugh concealed his involvement in this transaction from his business associates at PCLS.

244. Florete sent his first samples to PCLS on July 29, 2013. From then until December 16, 2014, PCLS submitted over 3,900 claims to Medicare for tests conducted on samples provided by Florete's practice. Medicare paid PCLS over $1 million for these claims.

### H. McHugh and Kumar Lend $50,000 to Physician

245. Dr. Sanker Jayachandran ("Jayachandran"), is a doctor in Munster, Indiana.

246. In or about mid-2014, McHugh and Kumar attempted to obtain Jayachandran's business for PCLS.

247. Jayachandran agreed to send samples to PCLS in exchange for a loan of $50,000 from McHugh and Kumar.

248. Jayachandran began sending his first samples to PCLS in late July 2014. Using personal email accounts as opposed to PCLS email accounts, Kumar sent McHugh a draft promissory note for Jayachandran on August 21, 2014.

249. On August 24, 2014, again using a personal email account, Kumar sent McHugh the promissory note, which had been signed by Jayachandran.

250. On August 29, 2014, McHugh wired Jayachandran $50,000. Kumar gave McHugh $25,000 for his share of the loan.

251. In October, PCLS Compliance discovered the loan and began investigating it. McHugh sent an email to Kumar expressing surprise that PCLS had found out about the loan.

252. Due to this financial relationship, PCLS would not take any more samples from Jayachandran.

253. Jayachandran's last sample was sent to PCLS on our around December 1, 2014.

254. PCLS submitted 24 claims to Medicare for tests conducted on samples provided by Jayachandran. Medicare paid PCSL $9,438 for these claims.

**COUNT I**
**(False Claims Act: Presentation of False Claims)**
**(31 U.S.C. § 3729(a)(1)(A)**

255. The United States incorporates by reference Paragraphs 1 through 254 above as if fully set forth in this Paragraph.

256. Defendant Smith knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States for UDTs that were false as a result of illegal kickbacks in the form of cash payment and computer hardware and software and related services to SSPA.

257. Defendants PCLS, McHugh and Kumar knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States for UDTs that were false as a result of illegal kickbacks in the form of UDT analyzers and related services that allowed physicians to bill Medicare for UDTs.

258. Defendants PCLS, McHugh and Kumar knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States for UDTs that were false as a result of illegal kickbacks in the form of fees that PCLS paid Kumar in exchange for arranging for and recommending that physicians order tests that were reimbursed by federal programs.

259. Defendants PCLS, McHugh and Kumar knowingly presented, or caused to be presented, false or fraudulent claims for payment or approval to the United States for UDTs that were false as a result of illegal kickbacks in the form of loans to physician practices in exchange for referrals of UDTs to PCLS.

260. By virtue of the false or fraudulent claims that Defendants PCLS, Smith, McHugh and Kumar made or cause to be made, the United States suffered damages and therefore is

entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

**COUNT II**
**(False Claims Act: Presentation of False Statements Material to False Claims)**
**(31 U.S.C. § (a)(1)(B))**

261. The United States incorporates by reference Paragraphs 1 through 260 above as if fully set forth in this Paragraph.

262. Defendants PCLS, Smith, McHugh and Kumar knowingly made or caused to be made false records or statements material to false claims or fraudulent claims.

263. Defendants PCLS, Smith, McHugh and Kumar knowingly made or caused to be made false bills, requests for reimbursement, requisition forms, and records of service that were obtained by means of illegal kickbacks and were material to the payment or approval of claims by federal programs.

264. By virtue of the false or fraudulent statements that Defendants PCLS, Smith, McHugh and Kumar made or caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

**COUNT III**
**(Payment by Mistake of Fact)**

265. The United States incorporates by reference Paragraphs 1 through 264 above as if fully set forth in this Paragraph.

266. This is a claim for recovery of monies paid by the United States to Defendants as a result of mistaken understandings of fact.

267. The false claims which the Defendants submitted to the United States' agents were paid by the United States based upon mistaken or erroneous understandings of material fact.

268. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of Defendants' certifications and representations, paid Defendants certain sums of money to which they were not entitled, and Defendants are thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

## COUNT IV
**(Unjust Enrichment)**

269. The United States incorporates by reference Paragraphs 1 through 268 above as if fully set forth in this Paragraph.

270. This is a claim for the recovery of monies by which Defendants have been unjustly enriched.

271. By obtaining government funds to which they are not entitled, Defendants were unjustly enriched, and are liable to account and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

## PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants, jointly and severally, as follows:

I. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such further relief as may be just and proper.

II. On the Second Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such further relief as may be just and proper.

III. On the Third Count for payment by mistake, for the amounts the United States paid by mistake, plus interests, costs and expenses, and for all such further relief as may be just and proper.

IV. On the Fourth Count for unjust enrichment, for the amounts by which Defendants were unjustly enriched, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

Respectfully submitted,
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